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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH, CENTRAL DIVISION

KLEIN-BECKER usa, LLC, a Utah limited liability company, **Plaintiff,** **vs.** **ALLERGAN, INC., a Delaware corporation,** **Defendant.**	**SECOND AMENDED COMPLAINT** **AND** **JURY DEMAND** **Case No.: 2:03CV00514 DB** **Honorable Dee Benson** **Magistrate Brooke C. Wells**

Plaintiff Klein-Becker usa, LLC ("Klein-Becker" or "Plaintiff") complains of defendant Allergan, Inc. ("Allergan" or "Defendant") and alleges as follows:

PARTIES

1. Plaintiff, Klein-Becker, is a limited liability company organized and existing under the laws of the State of Utah, having a principal place of business at 5742 West Harold Gatty Drive, Salt Lake City, Utah 84116.

2. Defendant, Allergan, is a Delaware corporation, having a principal place of business at 2525 Dupont Drive, Irvine, California, 92623.

JURISDICTION AND VENUE

3. This is a civil action for damages and injunctive relief relating to violations of the Lanham Act, for Declaratory Judgment under the Declaratory Judgment Act, 28 U.S.C. § 2201, for cancellation of a trademark registration pursuant to 28 U.S.C. §§1064, 1119 and 1120, and for injunctive relief and damages under state law. Jurisdiction in this Court is founded under the Lanham Act, 15 U.S.C. §§ 1119, 1121, and 28 U.S.C. §§ 1331, 2201, 1338(a). Subject matter jurisdiction is also proper pursuant to 28 U.S.C. § 1332, because the parties are diverse, and the matter in controversy exceeds the sum or value of $75,000.

4. This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367, in that the state law claims are integrally related to the federal claims and arise from a common nucleus of operative facts, such that the resolution of all claims herein is in the interests of judicial economy.

5. This Court has personal jurisdiction over Defendant pursuant to the Utah Long Arm Statute, Utah Code Ann. § 78-27-24, because, *inter alia*, Defendant's sales and business in Utah are of such significance that Defendant is subject to general jurisdiction in this state. This Court also has personal jurisdiction over Defendant because, *inter alia*, it committed false

advertising in this State, knowingly threatened legal action against Plaintiff in this State, intentionally interfered with Plaintiff's relationships, and otherwise caused injury to Plaintiff in this State.

6. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) and (c).

GENERAL ALLEGATIONS

Plaintiff's Cosmetic Cream, StriVectin-SD®

7. Klein-Becker markets and sells a cosmetic cream known as StriVectin-SD®.

8. StriVectin-SD® is used to moisturize the skin and helps the skin rebuild collagen. Originally designed to reduce the appearance of stretch marks, it was ultimately determined that StriVectin-SD® effectively reduces the appearance of fine lines and wrinkles on the face.

9. Klein-Becker markets and promotes StriVectin-SD® in the skin-care segment of the cosmetic industry. StriVectin-SD® is sold over-the-counter in numerous retails stores and, since its introduction into the cosmetic market, has experienced remarkable sales and tremendous growth. Klein-Becker attributes much of StriVectin-SD®'s success in the marketplace to consumer demand for cosmetic products; the fact that Klein-Becker's cosmetic skin-cream works; the fact that Klein-Becker's cosmetic cream has been the subject of an unprecedented and unsolicited grass-roots word-of-mouth campaign and media attention; and Klein-Becker's advertising and market positioning. Klein-Becker does not market or promote StriVectin-SD® as a drug, or as a treatment for muscles under the skin.

"Botox," "Botox Cosmetic," and the Genesis of Allergan's Fraud on the Patent and Trademark Office

10. Allergan manufactures, markets and/or sells a drug known as "Botox," which is short for Botulinum Toxin Type A.

11. Botulinum Toxin Type A ("Botox") is derived from the Botulism bacteria, which is known to paralyze muscles and nerve endings. Due to the potentially dangerous nature of this bacteria, products derived from it are not sold over the counter or in pharmacies, but must be prescribed and administered by a physician. Since even sterilized derivatives of this bacteria may result in paralysis of muscles, Botox typically is administered by a physician using a syringe in order to accurately target the treatment area.

12. Unlike cosmetic wrinkle treatments, Allergan's Botox drug is not applied by consumers but must be administered by physicians; the drug does not treat a patient's skin or skin-related causes of wrinkles, such as collagen depletion; the use of the drug has risks and side effects; and the injections necessary to administer the drug are not available to or appropriate for everyone, but must be prescribed by a physician.

13. Drugs like Botox are regulated by the Federal Food and Drug Administration ("FDA"). Pursuant to FDA regulations, a drug is approved only for specific indications, and not for generalized use.

14. Indeed, as of December 1991, the FDA had only approved Botox for use in the treatment of bledpharaspams, strabismus, and cervical dystonia. At that time, the FDA did not approve Botox for the treatment of "wrinkles."

15. Notwithstanding the limited indications approved for Botox by the FDA, on January 3, 2001, Allergan filed a trademark application with the United States Patent and Trademark Office ("USPTO") for the mark "Botox," and falsely represented therein that Allergan had used and was using that mark to promote a drug for the treatment of "wrinkles"

since as early as 1990, and began using that mark in commerce for the treatment of "wrinkles" beginning in 1992. [*See* Allergan's registration, attached as Exhibit "A"].

16. In fact, Allergan was *not* using the Botox mark in commerce to promote the treatment of wrinkles in 1990 or 1992, and pursuant to FDA regulations, Allergan could not legally market, sell or advertise a drug under that mark for the treatment of "wrinkles" at that time.

17. As a result, Allergan's statements as represented in the trademark application for "Botox" were knowingly false.

18. In addition to providing the USPTO with knowingly false information, Allergan also withheld material information that would have permitted the USPTO to determine that Allergan had presented knowingly false information. These omissions included:

a. The Botox drug had not been approved by the FDA for the treatment of "wrinkles."

b. The Botox drug had not been lawfully used by Allergan for the treatment of "wrinkles."

c. No specimens—required examples showing the commercial use of the mark alleged in the application—had been submitted to the USPTO showing the use of the Botox drug on wrinkles.

19. In April 2002—more than a decade after Allergan represented to the USPTO it had started commercially using the mark "Botox" in connection with the treatment of "wrinkles"—the FDA approved the Botox drug for the temporary improvement of a specific muscular condition in certain adult patients that affects a very narrow portion of the face: severe to moderate "glabellar lines" (the deep vertical furrows or "vertical frown lines" between the

eyebrows) associated with corrugator and/or procerus muscle activity in patients between the ages of 18 and 65 years of age (the "FDA-approved use").

20. By providing knowingly false information to the USPTO, and by withholding other material information from the USPTO, Allergan committed a fraud on the USPTO. But for this fraud, Allergan would not have obtained a trademark registration for "Botox" relating to the treatment of "wrinkles." Moreover, the false statements in the registration evidence Allergan's intent to promote "Botox" in violation of FDA regulations.

Allergan is Prohibited by Law from Marketing, Promoting or Attempting to Market or Promote Its Botox Drug as a Cosmetic or for the Generalized Treatment of Wrinkles

21. Under federal law, Allergan is prohibited from marketing, promoting or attempting to market or promote its Botox drug for any non-FDA approved use, including without limitation marketing or promoting, or attempting to market or promote, its Botox drug as a cosmetic or for the general treatment of such things as fine lines, wrinkles or crows's feet.

22. The FDA regulations limit Allergan's ability to market and promote its Botox drug, *inter alia,* in order to protect the health and welfare of the public at large. These prohibitions also prevent Allergan from seeking to mislead the public into believing that its Botox drug is a cosmetic used to treat fine lines and wrinkles, and approved by the FDA for this purpose.

23. Nonetheless, to improperly and illegally expand the use of its Botox drug, Allergan set out to blur the markets for its Botox drug and the cosmetic skin-care market, particularly that segment of the market occupied by anti-wrinkle creams.

24. For example, even though a manufacturer of FDA approved products may not advertise a product for an "unapproved use," doctors and physicians are still able to prescribe drugs for "off-label uses." Physicians—Allergan's real consumers and the only group of consumers permitted by law to purchase Botox directly—are permitted to administer drugs for so-called "off-label uses" because they are presumed to fully understand the risks associated with administering a drug and are responsible for safeguarding the health and welfare of their patients. Thus, through such things as training physicians to administer "off-label uses" of its Botox drug and sponsoring physicians who promote "off-label uses," Allergan tries to indirectly achieve what FDA regulations forbid it to accomplish directly—that is, the promotion of "off-label uses" of Botox.

25. When the FDA approved Botox for use as a temporary muscle relaxant for the treatment of glabellar lines in April 2002, Allergan sought—and received—permission from the FDA to label this variant of its Botox drug "Botox Cosmetic" so that physicians could distinguish it from the use of Botox in connection with the treatment of bledpharaspams, strabismus, and cervical dystonia.

26. However, approval by the FDA to use a particular name in connection with the distribution of a drug to physicians and medical providers does not constitute an approval of such use pursuant to the Lanham Act and applicable case law relating thereto, nor does it absolve Defendant from claims of false advertising and unfair competition.

27. Nevertheless, after the FDA's approval of the Botox mark for the treatment of glabellar lines, Allergan began improperly promoting its drug as a cosmetic—under the misleading name "Botox Cosmetic"—for the generalized treatment of "wrinkles," even though

the FDA approved Botox solely as a drug and solely for the limited purposes of treating glabellar lines, not as a cosmetic, and not for the generalized treatment of "wrinkles."

28. By adding the term "cosmetic" to the name of its Botox drug and by unlawfully promoting its so-called "cosmetic" for the generalized treatment of "wrinkles," Allergan intended and has attempted to attract that segment of the public seeking a cosmetic treatment for fine lines, wrinkles or crow's feet. By using the term "cosmetic," Allergan also helped indoctrinate consumers to—and helped promote its Botox drug as—a medical treatment for fine lines, wrinkles or crow's feet, all of which are off-label uses of its drug that Allergan is prohibited by law from promoting.

29. Also, by mischaracterizing its drug as a "cosmetic," Allergan sought, *inter alia*, to downplay the risks and side effects of its Botox drug, and to overcome the natural resistance the public has to medical treatments that involve needles, prescriptions and injections.

30. The FDA has not approved Botox Cosmetic as a cosmetic, nor has it been approved for the generalized treatment of fine lines, wrinkles or crow's feet. In fact, the FDA has not approved the use of Botox Cosmetic to treat *any* "wrinkles," other than deep vertical furrows or "frown lines" caused by muscle contractions between the eyebrows (generally known as "glabellar lines") in some, but not all patients.

31. The FDA-approved use of Botox Cosmetic is limited by (a) the location of the line (between the eyebrows), (b) the severity of the line (severe to moderate), (c) the cause of the line (muscle contractions), and (d) the age of the patient (non-senior adult patients).

Allergan's Illegal Marketing Campaign

32. Notwithstanding the limited nature of the FDA's approval for Botox Cosmetic, Allergan embarked on an illegal pattern and practice of attempting to mislead consumers into believing that its product was approved and appropriate for the generalized treatment of fine lines, wrinkles and crow's feet.

33. On September 5, 2002, the FDA issued a "Warning Letter" to Allergan ordering it to stop using promotional materials that misleadingly suggested that Botox Cosmetic was "intended to treat the signs of aging" and intended for use "in all tough wrinkles." The FDA reminded Allergan of the limited purpose for which Botox Cosmetic had been approved and ordered that its advertisements truthfully reflect that limited approval. [*See* September 5, 2002 Letter from the FDA to Allergan, Inc., attached as Exhibit "B"].

34. Less than a year later, on June 23, 2003, the FDA issued yet another "Warning Letter" and again ordered Allergan to pull additional advertisements. This time, the FDA advised Allergan that "your journal advertisements are false and/or misleading because they falsely identify your product as a cosmetic treatment . . . ." [*See* June 23, 2003 Letter from the FDA to Allergan, Inc., attached as Exhibit "C"].

35. The FDA specifically restrained Allergan from generally promoting its drug for "frown lines" and "wrinkles," and from misbranding the use of its drug as a "cosmetic treatment." [*See* June 23, 2003 Letter, Ex. C (stating that "BOTOX® COSMETIC is not approved for the treatment of 'frown lines,'" and "[y]our advertisements misbrand your product by claiming that it is a cosmetic treatment.")].

36. Moreover, because FDA regulations prohibit Allergan's ability to market its drug as a "cosmetic," Allergan does not have a legally protected interest in the use of its Botox name in the cosmetic skin-care market, or in any market for the off-label uses of its drug.

37. Nonetheless, Allergan's efforts to blur the market, and to impermissibly promote its drug as a cosmetic, have caused harm to Klein-Becker by improperly attempting to compete with Klein-Becker in the cosmetic skin-care market, notwithstanding its legal inability to do so.

38. By way of example, Allergan itself has sponsored "studies"—conducted by physicians who promote and administer Botox—to compare the effectiveness of Botox Cosmetic to StriVectin-SD®, even though Allergan and the physicians associated with Allergan know that comparing Botox Cosmetic and StriVectin-SD® is improper.

Klein-Becker's Advertisements Differentiate the Markets and Ask the Public to Make an Informed Choice

39. After Allergan's persistent and unlawful incursions into the cosmetic market, Klein-Becker obviously had the First Amendment right to advertise and educate consumers of cosmetic products about the benefits of its cosmetic and the differences between its product and other products, including Allergan's Botox drug.

40. Klein-Becker developed its *Better than Botox?* advertising campaign to promote the benefits of Klein-Becker's cosmetic skin cream and to highlight the differences between StriVectin-SD® and Allergan's prescription Botox drug.

41. Klein-Becker's advertisements emphasize the benefits of using a non-invasive, non-prescription, cosmetic wrinkle cream over an invasive prescription drug that provides only temporary benefits while exposing the user to various potential risks and side effects. The comparisons are especially appropriate with respect to the treatment of the appearance of fine

lines, wrinkles and crow's feet—conditions for which no Botox drug has been approved but for which Allergan nevertheless promotes its Botox drug in violation of federal law.

42. StriVectin-SD®'s *Better than Botox?* advertisements ask the public—Klein-Becker's potential customers—to make an informed choice via a hypothetical question. The message is simple: If your concern is the appearance of fine lines, wrinkles or crow's feet, and/or you are risk adverse, you should try StriVectin-SD®. If your concern is "glabellar lines," deep furrows between the eyebrows, you should use Botox, as "StriVectin-SD has not been shown to eliminate the deep furrows targeted by Botox injections. . . ."

Allergan's Wrongful Threat of Litigation Against Klein-Becker

43. On or about May 19, 2003, Allergan sent a threatening letter to Klein-Becker asserting that certain claims made in StriVectin-SD® advertising were "false, misleading and completely without scientific merit." [*See* May 19, 2003 Letter from Allergan to Klein-Becker, attached as Exhibit "D"]. The Allergan letter goes on to threaten that the claims about StriVectin-SD® are "false and misleading, violative of § 43 of the Lanham Act and an Unfair Trade Practice under California Code § 17200." [*See* May 19, 2003 Letter, Ex. D].

44. The Allergan letter misrepresents the statements made in the StriVectin-SD® advertising, including taking statements out of context, repeating incomplete quotes in a misleading manner and making immaterial claims and distinctions.

45. Upon information and belief, the Allergan letter to Klein-Becker and its expressed and implied threats of litigation are and were part of an unlawful effort by Allergan to promote its drug as a cosmetic, to promote "off-label" uses of its drug, to suppress Klein-Becker's

commercial speech about its cosmetic product and Allergan's prescription drug, and to prevent or injure the sales of Klein-Becker's cosmetic skin-care products.

Allergan's Tortious Interference with Klein-Becker's Advertising

46. After Allergan's threatening letters to Klein-Becker did not achieve their wrongful purpose of suppressing Klein-Becker's commercial speech, Allergan decided to directly and indirectly interfere with Klein-Becker's ability to freely run its "*Better than Botox?*" advertising, and it took steps to prevent such advertising.

47. At all relevant times, Mediacom Worldwide, Inc. ("Mediacom") acted and/or served as an agent for Allergan. As such, Allergan is vicariously responsible for actions committed by Mediacom while being in an agency relationship.

48. Upon information and belief, Allergan, alone or in conjunction with Mediacom, (a) sent or caused to be sent letters or other communications to companies with whom Klein-Becker places advertising, which communications discuss and refer to the "*Better than Botox?*" advertising, and (b) had or caused to be had telephone conversations with companies with whom Klein-Becker places advertising, which conversations discuss and refer to the "*Better than Botox?*" advertising.

49. Allergan's direct and/or indirect contacts with the companies with whom Klein-Becker places advertising have included implied or express instructions to these companies not to accept the "*Better than Botox?*" advertising, and/or threats designed to intimidate or otherwise cause these companies to refuse to run the "*Better than Botox?*" advertising.

50. Among other things, Allergan and/or Mediacom demanded that companies with whom Klein-Becker places advertising not accept any advertisement which (a) uses the terms

Botox or "Botoxin," as they are "too close," in "copy points," and/or (b) states that Botox injections are "painful" and "irritating," as they supposedly are "virtually painless."

51. The statements made by Allergan, alone or in conjunction with Mediacom, to the companies with whom Klein-Becker places advertising, were false and/or misleading. Among other things, the assertion that Klein-Becker cannot use the name Botox in its advertisements is false, because a party may use the trademark and/or trade name of another in advertising, so long as the advertising is not contrary to law.

52. The assertion that Klein-Becker cannot use the name Botox or word "Botoxin" in its advertisements is also false, because Allergan has no *bona fide* trademark rights in the use of the word "Botox" in connection with the cosmetic industry.

53. Allergan's interference with Klein-Becker's advertising has had the desired effect: Publishers have refused to run StriVectin-SD®'s *Better than Botox?*" advertisements.

No Harm to Allergan by Klein-Becker's Advertising

54. In contrast, Allergan has not been harmed by Klein-Becker and its *Better than Botox?* advertisements. In fact, on information and belief, Allergan's sales of Botox have increased and continue to increase.

55. Klein-Becker's advertising targets those members of the consuming public who are seeking a non-invasive, over-the-counter cosmetic cream to help reduce the appearance of fine lines, wrinkles and crow's feet.

56. Allergan targets an entirely different sort of "consumer." Since Allergan's Botox drug must be prescribed and administered by a physician, Allergan targets physicians, and in particular, dermatologists, plastic surgeons, and other medical practitioners who treat patients

seeking to slow the effects of the aging process. As a class of consumers, these physicians are particularly sophisticated; they are presumed to be up-to-date with the latest techniques and, more importantly, they are supposed to be fully knowledgeable regarding the possible dangers and side effects associated with a particular treatment. It is this extraordinary level of sophistication that gives physicians the ability to use drugs, such as Allergan's Botox drug, in an off-label or non-FDA approved manner.

57. The physicians who purchase Allergan's Botox drug are sufficiently sophisticated to know that: (a) StriVectin-SD® is a cosmetic cream, not a drug; (b) StriVectin-SD® treats the skin, not the muscles under the skin as does Allergan's Botox drug; (c) StriVectin-SD® and Allergan's Botox drug were designed for different purposes; and (d) by virtue of the foregoing, attempting to compare StriVectin-SD® and Allergan's Botox drug is about as useful as comparing apples and oranges. Given this level of sophistication, the physicians who purchase Allergan's Botox drug are not likely to be confused by Klein-Becker's *Better than Botox?* advertisements.

58. Moreover, Allergan cannot lawfully promote its product in the market in which StriVectin-SD® competes—the cosmetic market for skin-care treatments. FDA regulations and the Lanham Act prohibit Allergan from lawfully competing in that market.

59. Allergan also has no trademark rights in the word "Botox" in connection with the sale of, or registration for, cosmetic and other related products. Allergan's fraud on the USPTO justifies invalidation of Allergan's fraudulent trademark registrations that include "wrinkles" in the description of goods and services. In addition, Allergan has no trademark rights in the word "Botox" where that mark has not been lawfully used in commerce. Where the mark owner may

not lawfully use or promote its product—as in the case of the FDA's prohibition against marketing and promoting off-label uses—the law will not recognize trademark rights.

60. Finally, Allergan cannot reasonably claim that Klein-Becker's *Better than Botox?* advertisements have resulted in confusion because the physicians who purchase Allergan's Botox drug are sufficiently sophisticated to know the difference between products. At the same time, however, Allergan's false advertising—giving the public the impression that its Botox drug is a cosmetic and is approved for the generalized treatment of "wrinkles"—has resulted in consumer confusion and caused harm to Klein-Becker.

FIRST CAUSE OF ACTION[1]
(Cancellation of Registered Trademark (15 U.S.C. §§ 1064, 1119, 1120))

61. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 59 as if fully set forth herein.

62. Allergan owns several federal trademark registrations, including but not limited to the following registrations (the "BOTOX Registrations"):

Reg. No.	Mark/Logo
2510675	BOTOX
2510673	BOTOX

63. Each of the BOTOX Registrations should be cancelled for numerous reasons, including without limitation: (a) Allergan's fraud on the USPTO (Allergan's knowingly false description of its use of the mark on goods or services in U.S. commerce); and (b) Allergan's unlawful use of the mark in violation of FDA regulations and Section 43(a) of the Lanham Act.

[1] Klein-Becker has renumbered its causes of action to conform to proof and to reflect the changes in this case since the filing of Allergan's Second Amended Counterclaim and the Court's denial of Klein-Becker's motion to dismiss Allergan's Second Amended Complaint without prejudice.

64. Allergan received the BOTOX Registrations as a proximate result of its fraud on the USPTO, and therefore each of the BOTOX Registrations should be cancelled or, in the alternative, restricted to lawful uses.

65. The BOTOX Registrations also should be canceled because Allergan has no lawful right to use the BOTOX Registrations in connection with the treatment of "wrinkles" or any other off-label use of its Botox drug. In order to obtain a trademark registration, Allergan must show that it is lawfully using the BOTOX Registrations in commerce. However, FDA regulations prohibit such use.

66. Allergan's wrongful conduct in attempting to obtain exclusive rights in the use of the term Botox for off-label uses of its drug in order to compete against cosmetic skin-care treatments was intentional and willful and calculated to harm persons and entities such as Klein-Becker and to mislead consumers for its own improper pecuniary benefit.

SECOND CAUSE OF ACTION[2]
(Lanham Act - 15 U.S.C. § 1125(a)—False Advertising & Unfair Competition)

67. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 65 as if fully set forth herein.

68. Defendant's acts constitute false advertising, false association and/or unfair competition under the Lanham Act.

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[2] The Court granted Allergan's motion to dismiss this cause of action without prejudice. In light of the Court's denial of Klein-Becker's motion to dismiss Allergan's false advertising and unfair competition claims for lack of standing, Klein-Becker amends and reasserts this cause of action on the basis that, while Allergan does not compete in, has no legal interest in, and has suffered no injury in the market in which it claims Klein-Becker has engaged in false advertising, Klein-Becker *does* compete in, *does* have a legally protected interest in, and *has* suffered an actual injury in the non-prescription cosmetic cream market in which Allergan has engaged in false advertising. To preserve its rights on appeal, Klein-Becker has left and has supplemented the allegations of its original Lanham Act unfair competition claim.

69. Among other things, Defendant has made false representations and assertions to both consumers to whom Klein-Becker advertises and to companies with whom Klein-Becker places advertising.

70. Among other things, Defendant has improperly promoted its drug as a cosmetic wrinkle treatment and has improperly asserted rights to interfere with and disrupt the sales of cosmetic products, including by misleading and confusing consumers and interfering with Klein-Becker's advertising.

71. Defendant has engaged in this activity knowingly, willfully, with actual malice, and in bad faith, so as to justify the assessment of treble damages against Defendant.

72. Defendant's actions have caused Klein-Becker harm and have resulted in an improper financial benefit and gain to Defendant, which amount should be disgorged.

73. Defendant's conduct was wrongful, malicious, fraudulent, deliberate, willful, intentional and/or incredible, which makes this case an exceptional one, entitling Klein-Becker to an award of attorney fees pursuant to the Lanham Act.

74. Defendant's actions have caused, and unless enjoined will continue to cause, irreparable damage, loss, and injury to Klein-Becker for which it has no adequate remedy at law.

THIRD CAUSE OF ACTION[3]
(Unfair Competition—Utah Common Law)

75. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 73 as if fully set forth herein.

76. Defendant's violations of the Lanham Act, as alleged above, also constitute a violation of Utah common law, have caused Klein-Becker harm and have resulted in an improper benefit and gain to Defendant, which amount should be disgorged.

77. Defendant has engaged in this activity knowingly, willfully, with actual malice, and in bad faith, so as to justify the assessment of increased, exemplary and punitive damages against Defendant, in an amount to be determined at trial.

78. Defendant's tortious actions have caused, and unless enjoined by this Court will continue to cause, irreparable damage, loss and injury to Klein-Becker for which it has no adequate remedy at law.

FOURTH CAUSE OF ACTION
(Utah Code Ann. § 13-5-1, *et seq.*—Utah Unfair Practices Act)

79. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 77 as if fully set forth herein.

[3] The Court granted Allergan's motion to dismiss this cause of action without prejudice. In light of the Court's denial of Klein-Becker's motion to dismiss Allergan's false advertising and unfair competition claims for lack of standing, Klein-Becker amends and reasserts this cause of action or on the basis that, while Allergan does not compete in, has no legal interest in, and has suffered no injury in the market in which it claims Klein-Becker has engaged in false advertising, Klein-Becker *does* compete in, *does* have a legally protected interest in, and *has* suffered an actual injury in the non-prescription cosmetic cream market in which Allergan has engaged in false advertising. To preserve its rights on appeal, Klein-Becker has left and has supplemented the allegations of its original Lanham Act unfair competition claim.

80. Defendant's acts constitute unfair methods of competition in commerce or trade, including because they offend public policy; they are immoral, unethical, oppressive, and/or unscrupulous; and/or they cause substantial injury to consumers.

81. Defendant's tortious actions have caused Klein-Becker harm.

82. Defendant has engaged in this activity knowingly, willfully, with actual malice, and in bad faith, so as to justify the assessment of increased, exemplary and punitive damages against Defendant, in an amount to be determined at trial.

83. Klein-Becker is entitled to recover three times the amount of actual damages sustained, or $2,000, whichever is greater, plus court costs.

84. Defendant's tortious actions have caused, and unless enjoined by this Court will continue to cause, irreparable damage, loss, and injury to Klein-Becker for which it has no adequate remedy at law.

85. Klein-Becker is also entitled to injunctive relief under Utah Code Ann. § 13-5-14.

FIFTH CAUSE OF ACTION
(Intentional Interference with Potential and Existing Economic Relations)

86. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 84 as if fully set forth herein.

87. As alleged above, Allergan and Mediacom have contacted companies with whom Klein-Becker places advertising and made certain statements and communications which have had the effect that these companies would not accept "*Better than Botox?*" advertising. Allergan has also contacted and made demands on retail clients of Klein-Becker, which has interfered with and disrupted one or more of Klein-Becker's business relationships.

88. Defendant's acts constitute an intentional interference with the existing and potential economic relations of Klein-Becker.

89. Defendant's interference was done with an improper purpose.

90. Defendant's interference was done by improper means.

91. As a direct and proximate cause of Defendant's acts, Klein-Becker has been harmed.

92. Defendant's acts were willful or malicious, or intentionally fraudulent conduct, or conduct that manifests a knowing and reckless indifference toward, and disregard of, Plaintiff's rights. Thus, Plaintiff is entitled to an award of punitive damages against Defendant under Utah Code Ann. § 78-18-1.

93. Defendant's actions have caused, and unless enjoined by this Court will continue to cause, irreparable damage, loss and injury to Klein-Becker for which it has no adequate remedy at law.

SIXTH CAUSE OF ACTION
(Intentional Interference with Potential and Existing Contractual Relations)

94. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 92 as if fully set forth herein.

95. As alleged above, Allergan and Mediacom have contacted companies with whom Klein-Becker places advertising, and made certain statements and communications which have had the effect that these companies would not accept "*Better than Botox?*" advertising. Allergan has also contacted and made demands on retail clients of Klein-Becker, which has interfered with and disrupted one or more of Klein-Becker's business relationships.

96. Defendant's acts constitute an intentional interference with the existing contractual relations of Klein-Becker.

97. Defendant's interference was done with an improper purpose.

98. Defendant's interference was done by improper means.

99. As a direct and proximate cause of Defendant's acts, Klein-Becker has been harmed.

100. Defendant's acts were willful or malicious, or intentionally fraudulent conduct, or conduct that manifests a knowing and reckless indifference toward, and disregard of, Plaintiff's rights. Thus, Plaintiff is entitled to an award of punitive damages against Defendant under Utah Code Ann. § 78-18-1.

101. Defendant's actions have caused, and unless enjoined by this Court will continue to cause, irreparable damage, loss, and injury to Klein-Becker for which it has no adequate remedy at law.

SEVENTH CAUSE OF ACTION
(Declaratory Relief)

102. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 100 as if fully set forth herein.

103. Contrary to Allergan's demands and allegations, there is no likelihood that Allergan's consumers (the physicians who purchase Allergan's Botox drug) will be confused by Klein-Becker's *Better than Botox?* advertising. Allergan's consumers are sufficiently sophisticated to know that: (a) StriVectin-SD® is a cosmetic cream, not a drug; (b) StriVectin-SD® treats the appearance of wrinkles, fine lines and crow's feet on the skin, and has no effect on the underlying muscles; and (c) unlike Klein-Becker's StriVectin-SD® cosmetic

cream, Allergan's Botox drug is capable of paralyzing the muscles under the skin and therefore suitable for reducing the appearance of glabellar lines caused by muscle contractions.

104. The fact that the physicians who purchase and administer Allergan's Botox drug must be fully aware of the side effects associated with that and any other treatment prior to administering same to their patients demonstrates conclusively that the physicians are not likely to be confused by Klein-Becker's *Better than Botox?* advertising, and will be in a position to advise their patients regarding treatment options.

105. Moreover, Allergan has no legitimate right to use the trademark "Botox" in the cosmetic industry. Trademark rights exist solely through lawful use, and the FDA regulations prohibit Allergan from promoting and marketing its Botox drug for off-label uses, including without limitation the suggestion that Botox is a cosmetic.

106. On the other hand, Allergan's improper use of the term "cosmetic" in connection with its Botox drug constitutes false advertising and unfair competition in violation of §43(a) of the Lanham Act, 15 U.S.C. §1125(a).

107. There is a *bona fide*, present and actual need for this declaration based on the disputes between Klein-Becker and Allergan.

108. Absent any confusion by Allergan's consumers (*i.e.,* the physicians), and in light of Allergan's wrongful conduct, Klein-Becker is entitled the entry of a declaratory judgment providing that:

a. Klein-Becker's *Better than Botox?* and related StriVectin-SD® advertising is not false, deceptive or misleading;

b. Allergan does not have a legally protected interest in the market for cosmetic products;

c. Allergan does not have a legally protected interest in the market for products that treat the appearance of fine lines, wrinkles or crow's feet;

d. Allergan has not suffered any harm from any advertising of StriVectin-SD®;

e. Klein-Becker can use the term Botox in its advertisements;

f. Allergan has unlawfully used the mark "BOTOX® Cosmetic" to promote its drug;

g. Allergan has unlawfully promoted Botox injections as a cosmetic wrinkle treatment;

h. It would be unreasonable for Allergan's consumers (*i.e.,* physicians) to confuse Klein-Becker's cosmetic cream StriVectin-SD® with Allergan's Botox Cosmetic drug, based on Klein-Becker's "*Better than Botox?*" advertisements;

i. Klein-Becker's "*Better than Botox?*" advertisements do not dilute (*i.e.,* tarnish or blur) Allergan's alleged mark "Botox";

j. Klein-Becker is not liable for any claims of false advertising, false association, unfair business practices, unfair competition, trademark infringement or dilution for any advertising of StriVectin-SD® under § 43 of the Lanham Act, or any other provision of the Lanham Act;

k. Klein-Becker is not liable for false advertising or unfair business practices for any advertising of StriVectin-SD® under California Business and Professional Code Section 17200, or any other provision of California, Utah or Federal law, or the law of any other jurisdiction;

l. Allergan should pay Klein-Becker its attorney fees and costs incurred in prosecuting this action; and

m. Klein-Becker is entitled to such other and further relief as the Court may deem proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for an Order and Judgment as follows:

I. On the First Claim for Relief, for a Judgment in favor of Klein-Becker and against Allergan canceling or limiting Allergan's Botox registrations, and for other relief as appropriate;

II. On the Second, Third, Fourth, Fifth, and Sixth Claims for Relief, for a Judgment in favor of Klein-Becker and against Allergan in an amount to be determined at trial, including without limitation compensatory, treble and punitive damages, any other statutory enhancement, attorney fees and litigation costs, and for injective relief as pled and appropriate.

III. On the Seventh Claim for Relief, for a Declaratory Judgment and other relief as appropriate.

IV. For attorney fees and costs as allowed by law.

V. For additional relief as the Court determines just and equitable in the premises.

JURY DEMAND

Klein-Becker requests a jury on all issues so triable.

MAGLEBY & GREENWOOD, P.C.

James E. Magleby
Christine T. Greenwood
Jason A. McNeill
Sharee O. Moser
Attorneys for Plaintiff and Counterclaim Defendant
Klein-Becker, usa, LLC

CERTIFICATE OF SERVICE

I hereby certify that I am employed by the law firm of Magleby & Greenwood, P.C., 170 South Main Street, Suite 350, Salt Lake City, Utah 84101, and that pursuant to Rule 5(b), Federal Rules of Civil Procedure, a true and correct copy of the foregoing **SECOND AMENDED COMPLAINT AND JURY DEMAND** was delivered to the following this 16th day of September 2005 by:

[ ] Hand Delivery

[ ] Facsimile No. (as indicated below)

[X] Depositing the same in the U.S. Mail, postage prepaid

[ ] Federal Express

[ ] Certified Mail, Receipt No. _____, return receipt requested

[X] By electronic mail (as indicated below)

Perry J. Viscounty
perry.viscounty@lw.com
Mark Finkelstein
mark.finkelstein@lw.com
Michele Johnson
michele.johnson@lw.com
LATHAM & WATKINS, LLP
850 Town Center Drive, 20th Floor
Costa Mesa, California 92626-1925
Telephone: 714.540.1235
Facsimile: 714.755.8290

Attorneys for Defendant and Counterclaim Plaintiff Allergan, Inc.

Bryon J. Benevento
bbenevento@swlaw.com
Kimberly A. Neville
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SNELL & WILMER, LLP
15 W. South Temple, Suite 1200
Salt Lake City, Utah 84101
Telephone: 801.257.1900
Facsimile: 801.257.1800

Attorneys for Defendant and Counterclaim Plaintiff Allergan, Inc.

Exhibit "A"

Int. Cl.: 5

Prior U.S. Cls.: 6, 18, 44, 46, 51 and 52

Reg. No. 2,510,673

United States Patent and Trademark Office

Registered Nov. 20, 2001

TRADEMARK
PRINCIPAL REGISTER

BOTOX

ALLERGAN, INC. (DELAWARE CORPORATION)
2525 DUPONT DRIVE
IRVINE, CA 92612

FOR: PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS, MUSCLE DYSTONIAS, SMOOTH MUSCLE DISORDERS,AUTONOMIC NERVE DISORDERS, HEADACHES, WRINKLES, HYPERHYDROSIS, SPORTS INJURIES, CEREBRAL PALSY, SPASMS, TREMORS AND PAIN, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 3-31-2000; IN COMMERCE 11-15-2000.

OWNER OF U.S. REG. NOS. 1,692,384, 1,709,160 AND OTHERS.

SER. NO. 78-041,612, FILED 1-3-2001.

JENNIFER KRISP, EXAMINING ATTORNEY

78041612

<SERIAL NUMBER> 78041612
<FILING DATE> 01/03/2001

<DOCUMENT INFORMATION>
<TRADEMARK/SERVICEMARK APPLICATION>
<VERSION 1.22>

<APPLICANT INFORMATION>
<NAME> Allergan, Inc.
<STREET> 2525 Dupont Drive
<CITY> Irvine
<STATE> CA
<COUNTRY> USA
<ZIP/POSTAL CODE> 92612
<TELEPHONE NUMBER> 714-246-4500
<FAX NUMBER> 714-246-4249
<E-MAIL ADDRESS> hinchey_susan@allergan.com

<APPLICANT ENTITY INFORMATION>
<CORPORATION: STATE/COUNTRY OF INCORPORATION> Delaware

<TRADEMARK/SERVICEMARK INFORMATION>
<MARK> BOTOX
<TYPED FORM> No
* Applicant requests registration of the above-identified trademark/service mark in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq., as amended). *

<BASIS FOR FILING AND GOODS/SERVICES INFORMATION>
<USE IN COMMERCE: SECTION 1(a)> Yes
* Applicant is using or is using through a related company the mark in commerce on or in connection with the below-identified goods/services. (15 U.S.C. Section 1051(a), as amended.). Applicant attaches one SPECIMEN for each class showing the mark as used in commerce on or in connection with any item in the class of listed goods and/or services. *
<SPECIMEN> Yes
<SPECIMEN DESCRIPTION> Digitally photographed carton
<INTERNATIONAL CLASS NUMBER> 005
<LISTING OF GOODS AND/OR SERVICES> Pharmaceutical preparations for the treatment of neurological disorders, muscle dystonias, smooth muscle disorders,autonomic nerve disorders, headaches, wrinkles, hyperhydrosis, sports injuries, cerebral palsy, spasms, tremors and pain
<FIRST USE ANYWHERE DATE> 03/31/2000
<FIRST USE IN COMMERCE DATE> 11/15/2000

<OPTIONAL INFORMATION>
<PRIOR REGISTRATION(S)> "Applicant claims ownership of U.S. Registration Number(s) 1692384 1709160 1748079 and others."

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<NUMBER OF CLASSES PAID> 1
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<DEPOSIT ACCOUNT NUMBER> 010885
* The U.S. Patent and Trademark Office is hereby authorized to charge any fees or credit any overpayments to the deposit account listed above. *
<NAME OF PERSON AUTHORIZING ACCOUNT ACTIVITY> Susan J. Hinchey
<COMPANY/FIRM NAME> Allergan, Inc.

<LAW OFFICE INFORMATION>
* The USPTO is authorized to communicate with the applicant at the below e-mail address *
<E-MAIL ADDRESS FOR CORRESPONDENCE> hinchey_susan@allergan.com

<SIGNATURE AND OTHER INFORMATION>
* PTO-Application Declaration: The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements may jeopardize the validity of the application or any resulting registration, declares that he/she is properly authorized to execute this application on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered, or, if the application is being filed under 15 U.S.C. Section 1051(b), he/she believes applicant to be entitled to use such mark in commerce; to the best of his/her knowledge and belief no other person, firm, corporation, or association has the right to use the mark in commerce, either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods/services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true. *
<SIGNATURE> /Martin A. Voet/
<DATE> 01/03/2001
<NAME> Martin A. Voet
<TITLE> Assistant Secretary

<MAILING ADDRESS>
<LINE> Allergan, Inc.
<LINE> 2525 Dupont Drive
<LINE> Irvine CA 92612

78041612

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E-MAIL ADDRESS FOR ACKNOWLEDGMENT> hinchey_susan@allergan.com

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01/10/2001 6:42 AM

<SERIAL NUMBER> 78041612
<FILING DATE> 01/03/2001

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<NAME OF PERSON AUTHORIZING ACCOUNT ACTIVITY> Susan J. Hinchey
<COMPANY/FIRM NAME> Allergan, Inc.

<LAW OFFICE INFORMATION>
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<E-MAIL ADDRESS FOR CORRESPONDENCE> hinchey_susan@allergan.com

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<SIGNATURE> /Martin A. Voet/
<DATE> 01/03/2001
<NAME> Martin A. Voet
<TITLE> Assistant Secretary

Internet Transmission Date:
2001/01/03

Serial Number:
78041612

78041612

Filing Date:
2001/01/03

TRADEMARK APPLICATION

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

TOTAL FEES DUE: $325

DEPOSIT ACCOUNT NUMBER: 010885

01032001

NO OCR

01-03-2001

Drawing Page

Serial Number:
78041612

78041612

Applicant:
Allergan, Inc.
2525 Dupont Drive
Irvine CA USA 92612

Date of First Use:
03/31/2000

Date of First Use in Commerce:
11/15/2000

Goods and Services:
Pharmaceutical preparations for the treatment of neurological disorders, muscle dystonias, smooth muscle disorders, autonomic nerve disorders, headaches, wrinkles, hyperhydrosis, sports injuries, cerebral palsy, spasms, tremors and pain

Mark:

BOTOX

NO OCR

PUBLISHED
8/28/01

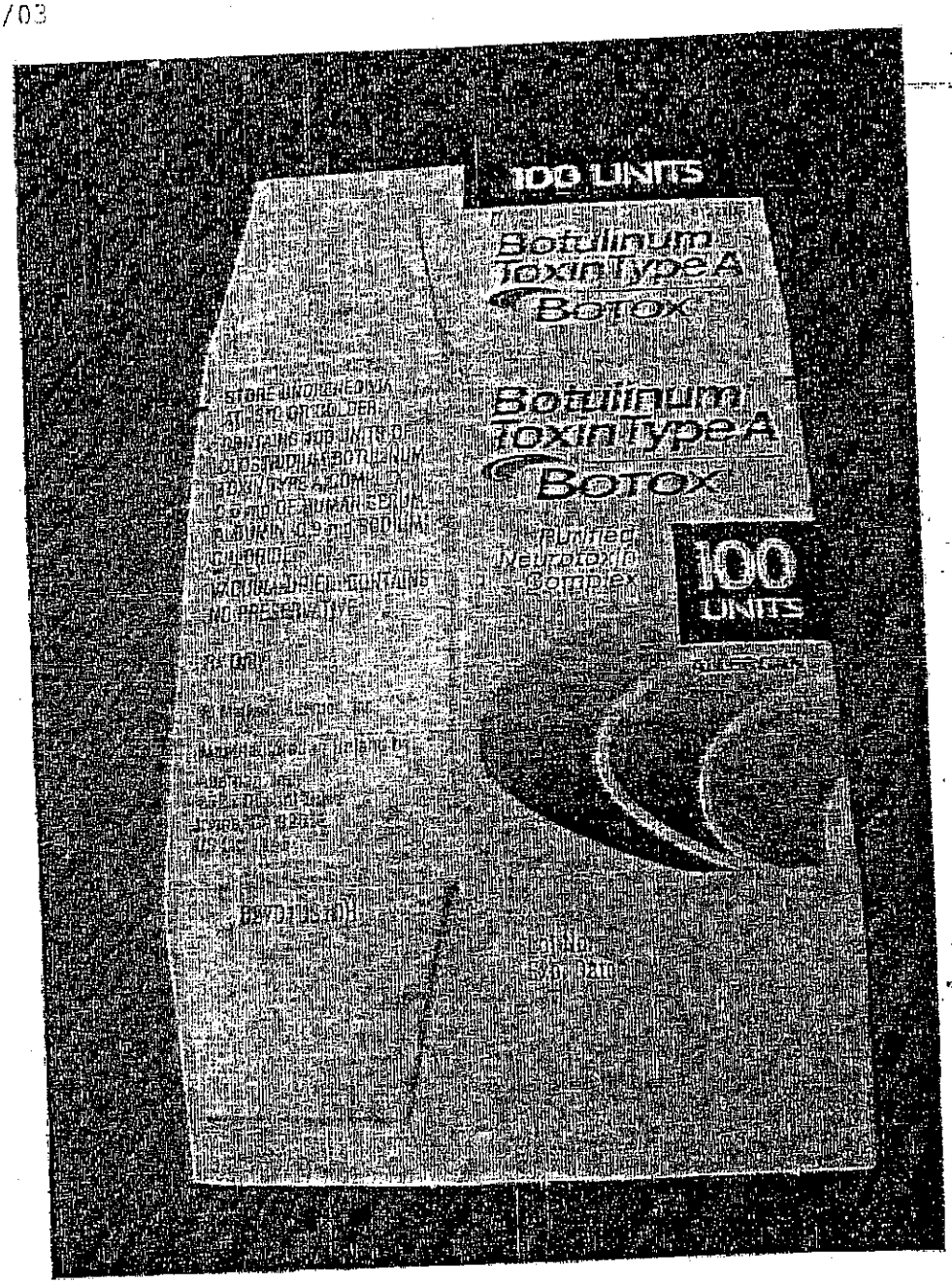
01032001

ORIGINAL SPECIML

Internet Transmission Date:
2001/01/03

Serial Number:
78041612

Filing Date:
2001/01/03



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<SERIAL NUMBER> 78041618
<FILING DATE> 01/03/2001

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<VERSION 1.22>

<APPLICANT INFORMATION>
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<STREET> 2525 Dupont Drive
<CITY> Irvine
<STATE> CA
<COUNTRY> USA
<ZIP/POSTAL CODE> 92612
<TELEPHONE NUMBER> 714-246-4500
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<TRADEMARK/SERVICEMARK INFORMATION>
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<TYPED FORM> Yes
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<SPECIMEN DESCRIPTION> Digitally photographed carton
<INTERNATIONAL CLASS NUMBER> 005
<LISTING OF GOODS AND/OR SERVICES> Pharmaceutical preparations for the treatment of neurological disorders, muscle dystonias, smooth muscle disorders, autonomic nerve disorders, headaches, wrinkles, hyperhydrosis, sports injuries, cerebral palsy, spasms, tremors and pain
<FIRST USE ANYWHERE DATE> 09/30/1990
<FIRST USE IN COMMERCE DATE> 01/22/1992

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<DATE> 01/03/2001
<NAME> Martin A. Voet
<TITLE> Assistant Secretary

<MAILING ADDRESS>
<LINE> Allergan, Inc.
<LINE> 2525 Dupont Drive
<LINE> Irvine CA 92612

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E-MAIL ADDRESS FOR ACKNOWLEDGMENT> hinchey_susan@allergan.com

Exhibit F

Int. Cl.: 5

Prior U.S. Cls.: 6, 18, 44, 46, 51 and 52

Reg. No. 2,510,675

United States Patent and Trademark Office

Registered Nov. 20, 2001

TRADEMARK
PRINCIPAL REGISTER

BOTOX

ALLERGAN, INC. (DELAWARE CORPORATION)
2525 DUPONT DRIVE
IRVINE, CA 92612

FOR: PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF NEUROLOGICAL DISORDERS, MUSCLE DYSTONIAS, SMOOTH MUSCLE DISORDERS, AUTONOMIC NERVE DISORDERS, HEADACHES, WRINKLES, HYPERHYDROSIS, SPORTS INJURIES, CEREBRAL PALSY, SPASMS, TREMORS AND PAIN, IN CLASS 5 (U.S. CLS. 6, 18, 44, 46, 51 AND 52).

FIRST USE 9-30-1990; IN COMMERCE 1-22-1992.

OWNER OF U.S. REG. NOS. 1,692,384, 1,709,160 AND OTHERS.

SER. NO. 78-041,618, FILED 1-3-2001.

JENNIFER KRISP, EXAMINING ATTORNEY

<SERIAL NUMBER> 78041618
<FILING DATE> 01/03/2001

<DEPOSIT ACCOUNT INFORMATION>
<DEPOSIT ACCOUNT NUMBER> 010885
* The U.S. Patent and Trademark Office is hereby authorized to charge any fees or credit any overpayments to the deposit account listed above. *
<NAME OF PERSON AUTHORIZING ACCOUNT ACTIVITY> Susan J. Hinchey
<COMPANY/FIRM NAME> Allergan, Inc.

<LAW OFFICE INFORMATION>
* The USPTO is authorized to communicate with the applicant at the below e-mail address *
<E-MAIL ADDRESS FOR CORRESPONDENCE> hinchey_susan@allergan.com

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* PTO-Application Declaration: The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements may jeopardize the validity of the application or any resulting registration, declares that he/she is properly authorized to execute this application on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered, or, if the application is being filed under 15 U.S.C. Section 1051(b), he/she believes applicant to be entitled to use such mark in commerce; to the best of his/her knowledge and belief no other person, firm, corporation, or association has the right to use the mark in commerce, either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods/services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true. *
<SIGNATURE> /Martin A. Voet/
<DATE> 01/03/2001
<NAME> Martin A. Voet
<TITLE> Assistant Secretary

Internet Transmission Date:
2001/01/03

Filing Date:
2001/01/03

Serial Number:
78041618

78041618

TRADEMARK APPLICATION

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

TOTAL FEES DUE: $325

DEPOSIT ACCOUNT NUMBER: 010885

NO OCR

01032001

01-03-2001

Drawing Page

Serial Number:
78041618

78041618

Applicant:
Allergan, Inc.
2525 Dupont Drive
Irvine CA USA 92612

Date of First Use:
09/30/1990

Date of First Use in Commerce:
01/22/1992

Goods and Services:
Pharmaceutical preparations for the treatment of neurological disorders, muscle dystonias, smooth muscle disorders, autonomic nerve disorders, headaches, wrinkles, hyperhydrosis, sports injuries, cerebral palsy, spasms, tremors and pain

Mark:

BOTOX

NO OCR

PUBLISHED
08/28/01

01032001

01-03-2001

ORIGINAL SPECIML

Internet Transmission Date:
2001/01/03

Serial Number:
78041618

Filing Date:
2001/01/03

The applicant has submitted required color specimen. The USPTO has printed only one copy of the specimen, and extra copies can be produced in-house as needed.

Exhibit "B"

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Reseai
1401 Rockville Pike
Rockville MD 20852-1448

VIA FACSIMILE AND USPS

September 5, 2002

Mr. Peter A. Kresel
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92623-9534

Dear Mr. Kresel:

Through routine monitoring and surveillance the Advertising and Promotional Labeling Branch (APLB) of FDA's Center for Biologics Evaluation and Research has identified promotional materials for your product, BOTOX® COSMETIC Botulinum Toxin Type A, that are in violation of the Food, Drug and Cosmetic Act and its implementing regulations. APLB has reviewed several direct-to-consumer (DTC) promotional and broadcast (15 and 30 second air-time) pieces and has concluded that these materials contain misleading statements about BOTOX® Cosmetic. Copies of all referenced materials are enclosed.

Misleading statements:

"It seems like everybody is talking about Botox® Cosmetic, the highly effective, non-surgical procedure that can dramatically reduce your toughest wrinkle within 7 days." This statement is prominently presented at the beginning of the Patient Brochure (Tab A) and is misleading because it does not emphasize that this is a temporary procedure. In addition, the term "toughest wrinkle" does not adequately specify the approved indication for use and misleadingly suggests that Botox Cosmetic is for use in all tough wrinkles. Please immediately cease distribution of these, and similarly worded, materials and revise these statements to clearly emphasize the temporary duration of this product and to appropriately identify the approved indication for use, e.g. "those tough lines between your eyebrows."

"Is BOTOX® Cosmetic right for you? If doing all you can to look your best is important to you, Botox® Cosmetic may be for you." These statements in the Patient Brochure (Tab A) are misleading because they fail to state that the product is indicated for patients from 18 to 65 years of age. It is not until several pages later in the brochure that the approved age range is presented to the reader. Please revise this, and all similar presentations, at the time of your next printing to accurately and clearly define the approved population when discussing "Is BOTOX® Cosmetic ...right for you?"

The dilution table on the physician page of your website, www.botoxcosmetic.net, (Tab B) listing the amount of diluents to be added to the lyophilized vial of BOTOX® Cosmetic and the resulting dose in units per 0.1mL is misleading. The chart promotes four other dilutions and doses that are not approved for the glabellar lines indication for BOTOX® Cosmetic, which could confuse the physician and/or promote off-label use. Please immediately revise this chart to only include the approved dilution scheme. In addition, please revise the statement, "Recommended dose is 4 units at each of the 5 injection sites," to "recommended dose is 4.0 units per 0.1 mL at each of the 5 injection sites for a total treatment dose of 20 units in 0.5mL."

"So you can frown, smile, or look surprised—without the furrows, creases, and wrinkles." This and similar quotes were identified in your Patient Brochure, Quick Reference Guide, and Patient Education Video (Tabs A, C, and D). These statements do not adequately identify the approved indication for use and are misleading to the reader. Please revise this, and similar, statements to appropriately identify the approved indication for use, e.g. "...so you can frown, ..., and wrinkles between your eyebrows."

Violative Reminder Advertisements:

The "WOW" DTC television (TV) reminder advertisements (ads), transcripts in Tab E, are in violation of 21 CFR 202.1(e)(2)(i), regarding reminder advertisements. These ads, which 1) focus attention on complexion and image, 2) make repeated references to age, and 3) make the statement, "Ask your dermatologist or plastic surgeon about BOTOX Cosmetic" include the indication for use of the product. These examples strongly suggest that the product is intended to treat the signs of aging or glabellar lines.

Allergan should immediately stop all broadcasts of these ads and all other promotional activities for Botox Cosmetic that contain the same or similar presentations until such time that you have revised these, and all other relevant, pieces to comply with the applicable regulations and have submitted them to FDA.

This is not intended to be an all-inclusive list of deficiencies associated with your promotion of the above product. It is your responsibility to ensure that all materials distributed within the United States are in conformance with each requirement of the Act and applicable regulations.

You should respond in writing within ten days of the date of this letter. Your response should include a statement confirming that the requested items were immediately discontinued, of your intent to comply with each recommendation above, a list of all similarly violative materials, and a description of the method for discontinuation and the discontinuation date.

Your response should be directed by facsimile, to 301-827-3528, or in writing to Mr. Glenn N. Byrd, Chief, APLB, at the address listed on the following page. Should you

have any questions or concerns involving this matter, please contact Ms. Maryann Gallagher, Regulatory Review Officer at 301-827-3028.

Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Case Management
Advertising and Promotional Labeling Branch, HFM-602
1401 Rockville Pike, 200S
Rockville, MD 20852-1448

Sincerely,

Kathleen M Lewis

for Mary A. Malarkey
Director, Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation
and Research

Enclosures

cc: Mr. David Garbe

Exhibit "C"

FDA U.S. Food and Drug Administration Department of Health and Human Services

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20852-1448

CBER-03-012

VIA FACSIMILE AND CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Peter A. Kresel
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92713-9534

Dear Mr. Kresel:

June 23, 2003

This Warning Letter objects to Allergan, Inc.'s dissemination of promotional materials for the marketing of BOTOX® COSMETIC Botulinum Toxin Type A. Specifically, we refer to three journal advertisements for BOTOX® COSMETIC titled, "People Like You" (BTXC142) and (BTXC140) and "We promised to grow old together, not look old together" (BTXC141) that have been disseminated in May and June 2003. The Advertising and Promotional Labeling Branch (APLB) in the Food and Drug Administration's (FDA's) Office of Compliance and Biologics Quality has reviewed these advertisements and has concluded that they are in violation of Section 502(n) of the Federal Food, Drug and Cosmetic Act (the "Act") and its implementing regulations.

The agency has concluded that your journal advertisements are false and/or misleading because they falsely identify your product as a cosmetic treatment, fail to reveal material facts about the product's use, and minimize the risk information presented.

Moreover, we remind you that APLB previously objected, in an untitled letter dated September 5, 2002, to your dissemination of promotional materials for BOTOX® COSMETIC that failed to appropriately communicate the approved indication for use.

We are very concerned that by continuing to promote BOTOX® COSMETIC in a false and misleading manner these materials are raising significant public health concerns.

Background

Botulinum Toxin Type A is a drug under section 201(g) of the Food, Drug, and Cosmetic Act (the Act) [21 U.S.C.§ 321(g)] and a biologic, as defined in section 351(i) of the Public Health Service Act, (PHS Act) [42 U.S.C..§ 262]. On December 9, 1991, BOTOX® was approved for

the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia and the treatment of strabismus and blepharospasm associated with dystonia. On April 12, 2002, a supplement to the Botulinum Toxin Type A license application was approved for treatment of glabellular lines. Under this approval, Botulinum Toxin Type A is marketed and labeled for this new indication as BOTOX® COSMETIC.

Misbranding Your Product

Your advertisements misbrand your product by claiming that it is a cosmetic treatment, e.g., "More than half a million people have already been wowed by BOTOX® COSMETIC, America's most popular cosmetic treatment [emphasis added]". Your product is a drug as defined in section 201(g) of The Act and a biologic, as defined in section 351(i) of the PHS Act. Your advertisement and promotion of BOTOX® COSMETIC as a cosmetic treatment minimizes the risks associated with the use of this biological drug.

Overbroadening of Indication

Your advertisements misleadingly suggest that this drug is effective, for conditions beyond those that have been approved by the Food and Drug Administration.

The advertisements include the claims, "FDA-approved for the temporary treatment of frown line in people aged 18 to 65" and the phrases: "cause frown lines to form," and, "... the appearance of frown lines."

BOTOX® COSMETIC is not approved for the treatment of "frown lines." The approved indication for use is:

> "BOTOX® COSMETIC is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients::; 65 years of age."

In our previous untitled letter of September 5, 2002, FDA advised Allergan about the use of the correct indication statement. We stated:

"In addition, the term "toughest wrinkle" does not adequately specify the approved indication for use and misleadingly suggests that BOTOX® Cosmetic is for use in all tough wrinkles. Please imniediately cease distribution of these and similarly worded, materials and revise these statements... to appropriately identify the approved indication for use. .."

Allergan's response on October 18, 2002,

"As requested by the Agency, this revision will be made in subsequentlydistributed versions of this guide. It has already been revised on the BOTOX Cosmetic.net website."

Allergan continues to promote BOTOX® COSMETIC in a way that misrepresents the approved indications.

Minimization of risk information

The addition of the statement, ". ..if any occur. ..," to your fair balance statement minimizes important risks associated with the use of BOTOX® COSMETIC. In the absence of the presentation of more detailed data associated with the side effects that occur with this biological drug, the inclusion of this terminology minimizes the fact that adverse events do occur. In fact, the clinical trials supporting approval of the glabellar lines indication demonstrated that almost 44% of patients experienced some adverse event. The package insert states:

"In clinical trials of BOTOX® COSMETIC the most frequently reported adverse events

following injection of BOTOX® COSMETIC were headache, respiratory infection, flu syndrome, blepharoptosis and nausea." "Adverse events of any cause [randomized, multi-center, placebo controlled studies] were reported for 177 subjects treated (43.7%) N=405 and 54 placebo treated subjects (41.5%) N= 130." In addition, the package insert includes the following: "In the open-label, repeat injection study, ...adverse events of any type were reported for 49.1% (183/373) of subjects overall."

The statement, ". ..if any occur...," minimizes the data from the clinical trials which documented that almost one-half of all BOTOX® COSMETIC subjects exhibited adverse events.

Conclusions and Requested Actions

You have disseminated promotional journal advertisements that:

1. fail to disclose that BOTOX® COSMETIC is a biological drug,

2. omit important limitations on the indicated use of the product, and

3. minimize important risk information.

We request that you immediately cease dissemination of these, and all promotional materials that contain the same or similar violations outlined in this letter. You should provide a detailed response to the issues raised in this Warning Letter that includes:

1) Your agreement to immediately cease the dissemination of these advertisements in the magazines and on the your website, and all promotional materials now, and in the future, that contain the same or similar violations outlined in this letter.

2) Providing a plan of action to disseminate accurate and complete corrective information to the audience(s) to which you have disseminated the misleading messages. Any plan must include a specific timeline for implementation.

3) A written statement of your intent to immediately comply with the above requests.

Please respond in writing to APLB within 10 days of the date of this letter, of your intent to comply with APLB's request. If you have any questions or comments, please contact Glenn N. Byrd, MBA, RAC, Chief, APLB, or Maryann Gallagher, by facsimile at 301-827-3528, or at the address listed below.

We remind you that only written communications are considered official. Failure to respond to this letter may result in regulatory action, including seizure or injunction, without further notice.

Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality, Division of Case Management
Advertising and Promotional Labeling Branch, HFM-602
1401 Rockville Pike, 200S
Rockville, MD 20852-1448

Sincerely,

/s/

Steven A. Masiello

Director, Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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Exhibit "D"

ALLERGAN

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May 19, 2003

Dr. David B. Mowrey
Director of Scientific Affairs
Klein-Becker usa
5742 W. Harold Gatty Drive
Salt Lake City, Utah 84116

Re: Cease and Desist Order *Better than BOTOX Advertisements*

Dear Dr. Mowrey:

It has come to our attention that Klein-Becker has recently run extensive print advertising and blast emails for your StriVectin-SD skin care cream. In this advertisement (see attached copy) you make numerous false and misleading claims regarding your over the counter product versus our FDA approved drug/biologic BOTOX®. In your advertisement, you suggest StriVectin-SD is "Better than BOTOX®." Further, your medical spokesperson, Dr. Nathalie Chevreau, states that your product is "more effective than BOTOX®" and that BOTOX® effects "wear off the very next day."

Please be advised that we view these claims as false, misleading and completely without scientific merit. In fact, pursuant to the FDA approved label for BOTOX® Cosmetic, duration of effect is up to four months and no where is there any evidence of effects wearing off the next day. We are unaware in the volumes of published literature about BOTOX® or BOTOX® Cosmetic any well controlled and adequate clinical trials conducted that showed StriVectin-SD was more effective than BOTOX®. Of course, if you possess such data please forward your scientific evidence to my attention immediately.

Please be further advised that we request you cease and desist with these current advertising claims involving our product, BOTOX®. We consider your claims to be false and misleading, violative of §43 of the Lanham Act and an Unfair Trade Practice under California Code §17200.

If we do not receive your assurances within 14 days of your receipt of this letter that this advertisement and claims has been discontinued we reserve our right to take legal action under the above cited statutes against your company to further protect our rights.

We look forward to your prompt response and immediate corrective action.

Sincerely,

Steven A. Johnson
Vice President and Assistant General Counsel
Allergan, Inc.

/mm

Enclosures